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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,439

01/14/2005

Michio Mineshima

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9055

20374 7590 06/05/2009

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

06/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,439	<b>Applicant(s)</b> MINESHIMA ET AL.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/14/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Acknowledgements***

The Examiner acknowledges the reply filed 2/23/2009 in which no claims were amended. Currently claims 1, 2 and 5-11 are pending for examination in this application. Additionally, the Examiner also acknowledges the amendments to the specification and drawings filed 2/23/2009.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobsen et al. (USPN5,141,493). Jacobsen et al. discloses a closed circuit peritoneal dialysis system.

Regarding claims 7-11, Jacobsen et al. discloses a peritoneal dialysis system (Figures 1A-1B) comprising: a catheter (12) capable of injecting and discharging peritoneal dialysate in an abdominal cavity of a patient (patient, Figure 1A); a peritoneal dialysate circuit (primary circuit) external of the patient connected to the catheter (12); and a dialyzer provided in the peritoneal dialysate circuit (primary circuit, 1A); said dialyzer comprising a hemodialysate circuit (secondary circuit, 1B) connected via a hollow fiber membrane (24), characterized in that a means capable (196, 160, 28) of measuring a conductive osmotic agent concentration in peritoneal dialysate is provided

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in the peritoneal dialysate circuit on the side of the end at which the catheter (12) is connected for removal of water in the peritoneal dialysis circuit (cols 4-5) using microprocessor (220) controlled pumps (192, 16, 72) (Figures 1A-1B) with a calculating unit (cols 6-7) (Figure 1); and wherein the hemodialysate outflow from the dialyzer will be larger since the hemodialysate circuit removes water from the main patient circuit via the pump (16, 192) and the pressure valve (36) (col 4, ln 55-70).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-6 are rejected under 35 U.S.C 103(a) as being unpatentable over Jacobsen et al. (USPN5,141,493) in view of Karoor et al. (US2003/0105424).

Jacobsen et al. meets the claim limitations as described above except the multi-pump hemodialysate circuit.

However, Karoor et al. teaches a method and composition for removing toxins in dialysis.

Regarding claims 1-2 and 5-6, Karoor et al. teaches dialysis system (Figure 1) comprising: a catheter (24) capable of injecting and discharging fluid in an abdominal cavity of a patient (patient, Figure 1A); a primary circuit (10) external of the patient connected to the catheter (24); and a dialyzer provided in the primary circuit; said dialyzer comprising a hemodialysate circuit (12) connected via a hollow fiber membrane (20), the dialyzer system capable of removal of water in the peritoneal dialysis circuit ([0014]) using a pump (pump near NH3 filter) provided in a hemodialysate inflow channel to the dialyzer and a pump (lower pump near dialysate bags) provided in a hemodialysate outflow channel from the dialyzer, the pumps being driven so that a flux in the pump on the outflow channel side is larger than a flux in the pump on the inflow channel side (via the removal of water and toxins from the dialyzer, [0014], Figures 1-7).

At the time of the invention, it would have been obvious to replace the single pump (192) of Jacobsen et al. with the dual pump assembly in order to allow for controlled fluid flow and increased fluid pressure required for removal of larger molecules through the dialyzer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Karoor et al. ([0001-0010]).

***Response to Arguments***

Applicant's arguments filed 2/23/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Jacobsen et al. (USPN5, 141,493) reference does not disclose the means capable of measuring the osmotic agent concentration.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the prior art of record discloses several means capable of being used to measure the osmotic agent concentration. Jacobsen et al. discloses a device objective of being able to independently and separately control the concentration of the electrolyte and osmotic concentrations (col 2, ln 40-45). Jacobsen et al. further discloses that the pressures sensors (28, 160) can be used to determine to a transmembrane pressure which is indicative of an osmotic agent concentration (col 5, ln 1-10). Further Jacobsen et al. discloses that the additional sensors (load sensor 180) can be used to control and determine the concentration of the solution agents (col 7, ln 25-40).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

***Suggested Subject Matter***

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

The Examiner suggest further clarification of the measuring device with specific recitation of the operation/structure.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 6/4/2009

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763